

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

MDL No. 1456
Master File No. 1:01-CV-12257-PBS
Sub-Category Case No. 1:08-CV-11200

THIS DOCUMENT RELATES TO:

*United States ex rel. Linnette Sun and
Greg Hamilton, Relators*

v.
Baxter Healthcare Corporation

Judge Patti B. Saris

(Leave to File Granted August 22, 2011)

**BAXTER HEALTHCARE CORPORATION’S REPLY BRIEF
IN FURTHER SUPPORT OF ITS PARTIAL MOTION TO DISMISS**

In its Partial Motion to Dismiss, Baxter Healthcare Corporation (“Baxter”) demonstrated why Relators’ Recombinate claims are barred under the False Claims Act’s “first-to-file” bar, 31 U.S.C. § 3730(b)(5), by making a side-by-side comparison of the essential elements alleged in the Ven-A-Care Complaint¹ (“VAC Complaint”) and the Sun/Hamilton Complaint² (“Sun/Hamilton Complaint”). Relators’ Opposition cites readily distinguishable cases and ignores the fundamental argument that a resolution of the Ven-A-Care Complaint necessarily would foreclose the Sun/Hamilton Recombinate claims. Their opposition also fails to respond to our argument regarding the inappropriateness of Hamilton’s continued participation as a relator.

¹ Ven-A-Care Fourth Amended Complaint for Money Damages and Civil Penalties Under the False Claims Act, filed December 22, 2002 (Exhibit 2 to Baxter’s Partial Motion to Dismiss).

² Sun/Hamilton Complaint for Damages Under the Federal and Various State False Claims Act, filed April 22, 2005 in the District of Colorado (Exhibit 1 to Baxter’s Partial Motion to Dismiss).

I. ARGUMENT

A. Recombinate Should Be Dismissed from Count One

Confronted with Baxter's detailed comparison of the same essential elements contained in the two complaints, Relators attempt to weave a new allegation out of Ven-A-Care's old cloth. Relators apparently hope that by adding details concerning the same basic claims – about charge-back wholesalers and a consent decree between the DOJ and First DataBank, Inc. ("FDB") – they can transform an old inflated price reporting allegation into a brand new scheme. *See* Relators' Memorandum of Opposition to Baxter Healthcare Corporation's Partial Motion to Dismiss, (filed Aug. 11, 2011) ("Opp.") at 5. Relator's hope is misplaced.

In the first place, the Court's prior decision on our Motion to Dismiss rejected Relators' "new species" arguments. Moreover, the first-to-file bar focuses not on the details of the scheme, but rather on a comparison at a high level of generality. *See United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 32 (1st Cir. 2009) ("§ 3730(b)(5) can still bar a later claim even if that claim incorporates somewhat different details") (citation omitted); *United States ex rel. Folliard v. CDW Tech. Serv. Inc.*, 722 F. Supp. 2d 37, 41 (D.D.C. 2010) (because details may vary, two complaints should be compared "at a sufficiently high level of generality"). Relators rely on *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009), and *United States ex rel. Hutcheson v. Blackstone Medical*, 694 F. Supp. 2d 48 (D. Mass. 2010), *rev'd on other grounds*, No. 10-1505, 2011 U.S. App. LEXIS 10972 (1st Cir. June 1, 2011), but neither decision supports their argument.

Both *Duxbury* and *Hutcheson* did indeed find that a second complaint was not barred by an earlier one, but the facts were materially different. In *Duxbury*, the crucial distinction made between the two complaints was not, as Relators suggest, that the second complaint alleged

a scheme in greater detail. The first complaint alleged only that the defendant was using clinical trials to induce off-label use of their drug. The second complaint charged the defendant with a number of materially different promotional schemes: direct off-label marketing to medical professionals; influencing the results of purportedly independent clinical studies; illegal payments to medical professionals in the form of “educational grants” and “clerkships”; conducting unlawful rebate programs, and so forth. 579 F.3d at 33. Thus, the allegation in the first complaint plainly “fail[ed] to encompass the other allegations contained in the [second] Complaint.” *Id.*

Similarly, in *Hutcheson*, the court found the second complaint was not trumped by the first because the first complaint “made only passing ‘information and belief’ reference to false claims arising out of illegal kickbacks beyond Arkansas, [and] alleged a consulting agreement with only one doctor,” whereas the second complaint included specific and wide-ranging allegations of “research engagements, VIP travel, stock payments and royalties involving at least ninety-one doctors across the United States.” 694 F. Supp. 2d at 58-59.

Unlike the second complaints in those cases, the Sun/Hamilton Complaint merely fills in the details of conduct previously complained of in the VAC Complaint. The Sun/Hamilton Complaint, unlike the second complaints in *Duxbury* and *Hutcheson*, does not add any new essential elements, such as a new scheme or methodology. *Id.*; see also *United States ex rel. Westmoreland v. Amgen, Inc.*, 707 F. Supp. 2d 123, 130 (D. Mass. 2010) (finding second complaint was not barred under first-to-file bar because it included a widespread scheme and a new methodology not previously alleged), *aff’d in part, rev’d in part on other grounds*, *New York v. Amgen, Inc.*, 2011 U.S. App. LEXIS 15036 (1st Cir. July 22, 2011).

Relators claim that Baxter allegedly accomplished its scheme to inflate AWP by providing FDB a List Price for Recombinate, rather than the wholesaler acquisition cost (“WAC”) as required by FDB. *See* Opp. at 5. Although this court stated that Baxter’s reporting of misleading List Prices is an essential element of Relators’ claim, *see* March 25 Order, at *4, that essential element was already specified in the VAC Complaint. In fact, as Relators point out, the VAC Complaint “alleges at least four different kinds of possible misrepresentations in cost and price reporting to Medicare and Medicaid.” Opp. at 4. These include misrepresentations of “‘List Price,’ ‘Wholesale Net,’ Direct Price ‘DP’ or ‘DIRP,’ or Wholesaler Acquisition Costs, ‘WAC’ to which [drug pricing compendia] appl[ied] an industry average mark-up to establish an AWP.” Opp. at 4-5 (citing VAC Complaint, at ¶ 161b). Thus, not only does the VAC Complaint encompass the same essential element as the Sun/Hamilton Complaint, the VAC Complaint actually alleges *more* methods than the Sun/Hamilton Complaint, thereby presenting the exact *opposite* situation than that in *Duxbury* and *Hutcheson*.

Relators do not even address the notion that finding Baxter liable for Recombinate-related claims under the Sun/Hamilton Complaint would give rise to double recovery—a result the first-to-file rule statutorily prohibits. *See Erickson ex rel. United States v. American Inst. of Biological Sciences*, 716 F. Supp. 908, 918 (E.D. Va. 1989) (finding claims barred because both complaints alleged false claims based on improper payment of salaries and bonuses to INS employees, and would therefore lead to double recovery by the government). As Baxter has shown, both complaints allege false reporting that resulted in alleged inflated AWP, which, in turn, are claimed to have led to overpayments by the government. No matter the method, these overpayments will be the same in both cases: the amount by which the State or Federal Government over-reimbursed for Recombinate. These damages cannot be recovered twice. The

Relators' claims add no new purchasers to those alleged in the Ven-A-Care Complaint. Nor do Relators add any new purchases to those claimed by Ven-A-Care. Hypothetically, if Baxter were to resolve the Ven-A-Care case by settlement, Relators would be unable to point to any additional exposure not covered by that settlement that could form the basis for Relators' Recombinate claims. Relators' Recombinate claims are therefore barred.

B. Hamilton Should Be Dismissed as a Relator Because His "Original Source" Knowledge Is Limited to Recombinate

If Recombinate is removed from the case, the only therapy remaining is Advate. The Court previously ruled that Sun, not Hamilton, is an original source for Advate. *See* March 25 Order at *4. Relators have not—because they cannot—shown that Hamilton is an original source with respect to Advate.³ In fact, in their Opposition, Relators simply re-argue Hamilton's status as an original source for Recombinate, *See, e.g.*, Opp. at 2 ("Hamilton has provided direct and independent information regarding a specific AWP fraud scheme regarding Recombinate. As such he should remain a party to this action."); *id.* at 8 ("Since Sun/Hamilton's claims regarding Recombinate should not be barred by the First-to File [sic] provision of the FCA, Hamilton should not be dismissed as Relator."); *id.* at 9 ("Because the Recombinate allegations are not barred, Hamilton should not be dismissed from the case."). Because Hamilton is only an original source for Recombinate, if Recombinate is barred by the first-to-file provision of the FCA, Hamilton cannot remain a Relator in this case.

³ The only argument Relators make with respect to Advate is that Hamilton "held numerous meetings with Baxter regarding the 'pricing of several of the Baxter products discussed in the Complaint, including Advate.'" Opp. at 9. However, the substance of those discussions, as shown by the deposition testimony Relators attach to their brief, establishes only that Hamilton advised Baxter that its price to the market for Advate was too high to convince consumers to switch to it. Opp. at Ex. B. Nowhere does Hamilton's testimony reflect any knowledge that Baxter caused an inflated AWP for Advate to be reported by FDB or other drug pricing compendia.

II. CONCLUSION

Pursuant to 31 U.S.C. §3730(b)(5), this Court lacks jurisdiction over any Count 1 FCA allegations regarding Recombinate. Because Hamilton's status as an original source is based solely upon his information regarding Recombinate, Hamilton should similarly be dismissed from the case.

Respectfully submitted,

Dated: August 22, 2011

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CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing Baxter Healthcare Corporation's Reply Brief in Further Support of Its Partial Motion to Dismiss with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on August 22, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

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